

PATENT COOPERATION TREATY

From the INTERNATIONAL SEARCHING AUTHORITY

PCT

To: Mark Stirrat
Orrick, Herrington & Sutcliffe, LLP
4 Park Plaza, Suite 1600
Irvine, CA 92614-2558

NOTIFICATION OF TRANSMITTAL OF
THE INTERNATIONAL SEARCH REPORT AND
THE WRITTEN OPINION OF THE INTERNATIONAL
SEARCHING AUTHORITY, OR THE DECLARATION

(PCT Rule 44.1)

Date of mailing
(day/month/year)

23 NOV 2007

Applicant's or agent's file reference
CRMD-016WO

FOR FURTHER ACTION See paragraphs 1 and 4 below

International application No.
PCT/US 06/34130

International filing date
(day/month/year)

29 August 2006 (29.08.2006)

Applicant Cardiomind, Inc.

1. ☒ The applicant is hereby notified that the international search report and the written opinion of the International Searching Authority have been established and are transmitted herewith.

Filing of amendments and statement under Article 19:

The applicant is entitled, if he so wishes, to amend the claims of the international application (see Rule 46):

When? The time limit for filing such amendments is normally two months from the date of transmittal of the international search report.

Where? Directly to the International Bureau of WIPO, 34 chemin des Colombettes
1211 Geneva 20, Switzerland, Facsimile No.: +41 22 740 14 35

For more detailed instructions, see the notes on the accompanying sheet.

2. ☐ The applicant is hereby notified that no international search report will be established and that the declaration under Article 17(2)(a) to that effect and the written opinion of the International Searching Authority are transmitted herewith.

3. ☐ **With regard to the protest** against payment of (an) additional fee(s) under Rule 40.2, the applicant is notified that:

☐ the protest together with the decision thereon has been transmitted to the International Bureau together with the applicant's request to forward the texts of both the protest and the decision thereon to the designated Offices.

☐ no decision has been made yet on the protest; the applicant will be notified as soon as a decision is made.

4. **Reminders**

Shortly after the expiration of **18 months** from the priority date, the international application will be published by the International Bureau. If the applicant wishes to avoid or postpone publication, a notice of withdrawal of the international application, or of the priority claim, must reach the International Bureau as provided in Rules 90bis.1 and 90bis.3, respectively, before the completion of the technical preparations for international publication.

The applicant may submit comments on an informal basis on the written opinion of the International Searching Authority to the International Bureau. The International Bureau will send a copy of such comments to all designated Offices unless an international preliminary examination report has been or is to be established. These comments would also be made available to the public but not before the expiration of 30 months from the priority date.

Within **19 months** from the priority date, but only in respect of some designated Offices, a demand for international preliminary examination must be filed if the applicant wishes to postpone the entry into the national phase **until 30 months** from the priority date (in some Offices even later); otherwise, the applicant must, **within 20 months** from the priority date, perform the prescribed acts for entry into the national phase before those designated Offices.

In respect of other designated Offices, the time limit of **30 months** (or later) will apply even if no demand is filed within 19 months.

See the Annex to Form PCT/IB/301 and, for details about the applicable time limits, Office by Office, see the *PCT Applicant's Guide*, Volume II, National Chapters and the WIPO Internet site.

Name and mailing address of the ISA/US
Mail Stop PCT, Attn: ISA/US
Commissioner for Patents
P.O. Box 1450, Alexandria, Virginia 22313-1450
Facsimile No. 571-273-3201

Authorized officer:

Lee W. Young

PCT Helpdesk: 571-272-4300
PCT OSP: 571-272-7774

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference CRMD-016WO	FOR FURTHER ACTION	see Form PCT/ISA/220 as well as, where applicable, item 5 below.
International application No. PCT/US 06/34130	International filing date (<i>day/month/year</i>) 29 August 2006 (29.08.2006)	(Earliest) Priority Date (<i>day/month/year</i>) 02 November 2005 (02.11.2005)
Applicant Cardiomind, Inc.		

This international search report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This international search report consists of a total of 3 sheets.

☐ It is also accompanied by a copy of each prior art document cited in this report.

1. Basis of the report

a. With regard to the **language**, the international search was carried out on the basis of:

- ☒ the international application in the language in which it was filed.
☐ a translation of the international application into _____ which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).

b. ☐ This international search report has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43.6bis(a)).

c. ☐ With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, see Box No. I.

2. ☐ **Certain claims were found unsearchable** (see Box No. II).

3. ☒ **Unity of invention is lacking** (see Box No. III).

4. With regard to the **title**,

- ☒ the text is approved as submitted by the applicant.
☐ the text has been established by this Authority to read as follows:

5. With regard to the **abstract**,

- ☒ the text is approved as submitted by the applicant.
☐ the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box No. IV. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. With regard to the **drawings**,

- a. the figure of the **drawings** to be published with the abstract is Figure No. 9
☐ as suggested by the applicant.
☒ as selected by this Authority, because the applicant failed to suggest a figure.
☐ as selected by this Authority, because this figure better characterizes the invention.
- b. ☐ none of the figures is to be published with the abstract.

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 06/34130

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:
This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

Group I: claims 1-2 are directed to a power supply for an implant delivery system.

Group II: claims 3-38 are directed to a stent delivery system.

The inventions listed as Groups I-II do not relate to a single general inventive concept under PCT Rule 13.1 because under PCT Rule 13.2 they lack the same or corresponding technical features for the following reasons:

Groups II does not include the inventive concept of a power supply.

Groups I does not include the inventive concept of a stent delivery system.

1. ☒ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying additional fees, this Authority did not invite payment of additional fees.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.
- ☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
- ☒ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 06/34130

A. CLASSIFICATION OF SUBJECT MATTER

IPC(8) - A61F 2/06 (2007.10)

USPC - 623/1.11

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC(8) - A61F 2/06 (2007.10)

USPC - 623/1.11

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
424/423; 514/291, 604/500

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

PubWEST(USPT,PGPB,EPAB,JPAB); Google Scholar; Google

Search Terms Used: stent, sleeve, spring, eroding, erode, dissolve, dissolving, self expanding, alternating current, vessel, two phase

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5,643,254 A (SCHELDROP) 01 July 1997 (01.07.1997) Entire document, especially col 5, ln 28-65.	1 and 2
X -- Y	US 2005/0220836 A1 (FALOTICO et al.) 06 October 2005 (06.10.2005) para[0128], para[0396] and para[0437].	3-7 9 and 16-21
X -- Y	US 6,168,618 B1 (FRANTZEN) 02 January 2001 (02.01.2001) Entire document, especially col 3, ln 5-50 and col 7, ln 2-20.	8, 10, 12, 14, 15, 30 and 35-38 9, 11, 13, 16-29 and 31-34
Y	US 6,425,914 B1 (WALLACE et al.) 30 July 2002 (30.07.2002) FIG. 7 and col 7, ln 8-10.	11 and 34
Y	US 4,553,545 A (MAASS et al.) 19 November 1995 (19.11.1995) FIG. 8, FIG. 9 and col 12, 2-44.	13, 24-29 and 31-33
Y	US 2004/0260383 A1 (STELTER et al.) 23 December 2003 (23.12.2004) para[0033].	22-25

☐ Further documents are listed in the continuation of Box C.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search

10 October 2007 (10.10.2007)

Date of mailing of the international search report

23 NOV 2007

Name and mailing address of the ISA/US

Mail Stop PCT, Attn: ISA/US, Commissioner for Patents
P.O. Box 1450, Alexandria, Virginia 22313-1450

Facsimile No. 571-273-3201

Authorized officer:

Lee W. Young

PCT Helpdesk: 571-272-4300
PCT OSP: 571-272-7774

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

To: Mark Stirrat
Orrick, Herrington & Sutcliffe, LLP
4 Park Plaza, Suite 1600
Irvine, CA 92614-2558

Date of mailing
(day/month/year)

23 NOV 2007

Applicant's or agent's file reference
CRMD-016WO

FOR FURTHER ACTION

See paragraph 2 below

International application No.
PCT/US 06/34130

International filing date (day/month/year)
29 August 2006 (29.08.2006)

Priority date (day/month/year)
02 November 2005 (02.11.2005)

International Patent Classification (IPC) or both national classification and IPC
IPC(8) - A61F 2/06 (2007.10)
USPC - 623/1.11

Applicant **Cardiomind, Inc.**

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☒ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/US
Mail Stop PCT, Attn: ISA/US
Commissioner for Patents
P.O. Box 1450, Alexandria, Virginia 22313-1450
Facsimile No. 571-273-3201

Date of completion of this opinion

10 October 2007 (10.10.2007)

Authorized officer:

Lee W. Young

PCT Helpdesk: 571-272-4300
PCT OSP: 571-272-7774

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/US 06/34130

Box No. I Basis of this opinion

1. With regard to the **language**, this opinion has been established on the basis of:
 - ☒ the international application in the language in which it was filed.
 - ☐ a translation of the international application into _____ which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).
2. ☐ This opinion has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43bis.1(a))
3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, this opinion has been established on the basis of:
 - a. type of material
 - ☐ a sequence listing
 - ☐ table(s) related to the sequence listing
 - b. format of material
 - ☐ on paper
 - ☐ in electronic form
 - c. time of filing/furnishing
 - ☐ contained in the international application as filed
 - ☐ filed together with the international application in electronic form
 - ☐ furnished subsequently to this Authority for the purposes of search
4. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
5. Additional comments:

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/US 06/34130

Box No. IV Lack of unity of invention

1. ☒ In response to the invitation (Form PCT/ISA/206) to pay additional fees the applicant has, within the applicable time limit:
- ☒ paid additional fees
 - ☐ paid additional fees under protest and, where applicable, the protest fee
 - ☐ paid additional fees under protest but the applicable protest fee was not paid
 - ☐ not paid additional fees

2. ☐ This Authority found that the requirement of unity of invention is not complied with and chose not to invite the applicant to pay additional fees.

3. This Authority considers that the requirement of unity of invention in accordance with Rule 13.1, 13.2 and 13.3 is

☐ complied with

☒ not complied with for the following reasons:

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

Group I: claims 1-2 are directed to a power supply for an implant delivery system.

Group II: claims 3-38 are directed to a stent delivery system.

The inventions listed as Groups I-II do not relate to a single general inventive concept under PCT Rule 13.1 because under PCT Rule 13.2 they lack the same or corresponding technical features for the following reasons:

Groups II does not include the inventive concept of a power supply.

Groups I does not include the inventive concept of a stent delivery system.

None of these technical features are common to the other groups, nor do they correspond to a special technical feature in the other groups. Therefore, unity of invention is lacking.

4. Consequently, this opinion has been established in respect of the following parts of the international application:

☒ all parts

☐ the parts relating to claims Nos. _____

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.

PCT/US 06/34130

Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	6, 9, 11, 13, 16-29 and 31-34	YES
	Claims	1-5, 7, 8, 10, 12, 14, 15, 30 and 35-38	NO
Inventive step (IS)	Claims	None	YES
	Claims	1-38	NO
Industrial applicability (IA)	Claims	1-38	YES
	Claims	None	NO

2. Citations and explanations:

Claims 1 and 2 lack novelty under PCT Article 33(2) as being anticipated by US 5,643,254 A to Scheldrup et al. (hereinafter 'Scheldrup').

As per claim 1, Scheldrup describes a power supply for an implant delivery system employing at least one electrolytically erodable element (electrolytic detachment of an embolic device, (Abstract)), the improvement comprising: adaptation of the power supply to provide an AC voltage profile with a peak-to-peak configuration of at least about 5V (the amplifier delivers constant DC current with AC superposition, (col 7, ln 14-16); A positive electric current ... at 0.1-6 volts, (col 5, ln 28-30)) and a DC voltage signal of at least about 1V (A DC current of between ... 0.1 to 6 volts, (col 5, ln 63-65)).

As per claim 2, Scheldrup describes method of implant delivery, the method comprising: introducing an implant delivery system in an electrolytic fluid (Electrolytic separation of a device from a guidewire may be facilitated by means of the assembly 100 shown in FIG. 2, (col 3, ln 55-58)); and applying electrical power to an electrolytically erodable member, the power AC voltage profile with a peak-to-peak configuration of at least about 5V (the amplifier delivers constant DC current with AC superposition, (col 7, ln 14-16); A positive electric current ... at 0.1-6 volts, (col 5, ln 28-30)), and a DC voltage signal of at least about 1V (A DC current of between ... 0.1 to 6 volts, (col 5, ln 63-65)).

Claims 3-5 and 7 lack novelty under PCT Article 33(2) as being anticipated by US 2005/0220836 A1 to Falotico et al. (hereinafter 'Falotico').

As per claim 3, Falotico describes a method of loading a self-expanding stent (stent 100 ... may be made self-expanding, para[0128]) onto a delivery guide (insertion in a blood vessel or other tissue by insertion means, wherein the insertion means include a suitable catheter, or flexible rod, para[0128]), the method comprising: holding the stent compressed to a reduced diameter configuration (stent 100 has been formed it may be compressed, para[0128]) in at least one sleeve (the stent to include one or more ... sleeves, para[0396]; engaging the stent with the delivery guide (a suitable catheter, or flexible rod, para[0128]); and twisting the stent while in the sleeve (twisting it into a braided configuration, para[0128]).

As per claim 4, Falotico describes the method of claim 3, further comprising compressing the stent before loading the stent (after the stent 100 has been formed it may be compressed so as to occupy a space sufficiently small as to permit its insertion in a blood vessel or other tissue by insertion means, para[0128]) into the at least one sleeve (the stent to include one or more ... sleeves, para[0396]).

As per claim 5, Falotico describes the method of claim 3, wherein a plurality of sleeves hold the stent (the stent to include ... sleeves ... for positioning a system component, para[0396]).

As per claim 7, Falotico describes the method of claim 3, further comprising removing the at least one sleeve from the stent (delivery of self-expanding stents which typically require the retraction of a delivery sheath, para[0439]).

Claim 6 lacks an inventive step under PCT Article 33(3) as being obvious over Falotico. Falotico describes a method of claim 5 wherein the stent is twisted (twisting it into a braided configuration, para[0128]) and has a plurality of sleeves (the stent to include one or more ... sleeves, para[0396]). It would have been obvious to one skilled in the art to twist the stent by rotating the sleeves which cover them.

Claims 8, 10, 12, 14, 15, 30 and 35-38 lack novelty under PCT Article 33(2) as being anticipated by US 6,168,618 B1 (Frantzen).

As per claim 8, Frantzen describes a stent delivery system comprising: a delivery guide body having a distal portion (distal end 22 of catheter 21, (col 3, ln 32-46) and at least one elongate member including an electrolytically erodable section (binding straps 30 to erode via electrolytic action, (col 3, ln 10-15)); a stent comprising a near end, a far end and a structure extending therebetween (stent 10, FIG. 2, (col 3, ln 15-22)), at least one of the near and far end of the stent held in contact with the elongate body; wherein release of the erodable section initiates stent release (straps that causes them to erode, thus permitting the stent to partially or fully expand (col 3, ln 5-8)).

As per claim 10, Frantzen describes the system of claim 8, wherein at least one elongate member passes through the near or far end of the stent (guide wire 40, FIG. 2).

-----Please See Supplemental Box-----